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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,535	10/30/2003	David T. Curiel	678503-2001.1	7880

7590 01/10/2008
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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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01/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/697,535	Applicant(s) CURIET ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-32,34-44,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43,44 and 48 is/are allowed.
- 6) ☒ Claim(s) 25,27-32,34-42 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2007 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

3. Claims 25, 27-32, 34-42, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25, from which claims 27-32 depend, has been amended to recite that the adenovirus has a "deletion of nucleotides ranging from 324 to 488 of the adenoviral subtype 5 genome". It appears this language was intended to mean that nucleotides 324 to 488 of the adenoviral subtype 5 genome are deleted (see rejection under 35

USC 112, second para. below). Applicant points to Example 13 and Fig. 23 as support for this amendment.

As stated in the prior Office Action, claim 25 combines this deletion of the E1A promoter with the limitation that the tumor-specific promoter is operably linked to one or more early genes from E1, E2 and E4. Example 13 and Fig. 23 only describe replacing nucleotides 324 to 488 with the tumor-specific promoter, e.g. VEGF promoter. It is noted that claim 25 as amended is now limited to wherein the tumor-specific promoter driving the transcription of a gene is now limited to wherein the gene is an early E1 gene. However, as was previously stated, even where the promoter is operably linked to E1 (as now amended), there is no clear support for inserting the tumor-specific promoter anywhere but in place of the deleted nucleotides 324 to 488.

Furthermore, since the instant claims are not limited to a specific sequence which defines the nucleotide structure, it is unclear which nucleotides the nucleotides 324 to 488 correspond to. Therefore, the limitation in claim 25 may also be construed to mean that the Ad5 genome has a deletion of from 324 nucleotides to 488 nucleotides at any unspecified location. The limitations in claims 25 and 34 may also be construed to mean that the Ad5 genome has a deletion in the region of its nucleotides 324 to 488 (as now recited in the instant claims). See rejection under 35 USC 112, second para. below. However, to the extent that the claims as now amended do not reflect that the deletion corresponding to nucleotides 324 to 488 correspond to the Ad5 genome, and wherein the deletion is in the region of the E1A promoter, the claims now suggest that the

deletion of nucleotides 324 to 488 in the Ad5 genome does not necessarily require that the deletion be in the region of the E1A promoter.

Consequently, there is no evidence from the original specification that Applicant had contemplated or possessed this genus as broadly as it is claimed.

Claim 43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action of 11/20/06. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Applicant's arguments filed 10/12/07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the specification teaches the preparation and use of different promoters in conjunction with modified fiber domains in conditionally replicative adenoviral vectors in order to increase promoter activation specificity (see e.g., Examples 11-14). However, contrary to Applicant's assertions, this disclosure is not sufficient to provide explicit or implicit support for the specific limitations recited in the instant claims.

See MPEP § 2163.05 [R-2].II., citing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996), which states "[a] 'laundry list' disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not 'reasonably lead' those skilled in the art to any particular species."

With respect to claims 43, it was stated in the prior Office Action that the general statements in ¶¶ 0072 and 0086 do not direct one of skill in the art to prepare and use a conditionally replicative Ad5 vector with a chimeric Ad5/CAV-2 fiber and an E1A promoter replaced with a promoter from a gene encoding prostate specific antigen, carcinoembryonic antigen, secretory leukoprotease inhibitor, alpha-fetoprotein, or vascular endothelial growth factor. Rather the specification explicitly teaches using an Ad5 with a chimeric Ad5/CAV-2 fiber in conjunction with having an E1A promoter replaced by a CXCR4 or survivin promoter. Applicant has not indicated where the specification teaches generally that the chimeric Ad5/CAV-2 fiber be used in conjunction with other promoters. Although Claim 44 was amended to limit the promoter region to a gene encoding a CXR4 and survivin genes, claim 43 was not amended, and still recites wherein the promoter is from a gene encoding prostate specific antigen, carcinoembryonic antigen, secretory leukoprotease inhibitor, alpha-fetoprotein, and VEGF.

5. Claims 25, 27-32, 34-42, and 47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Applicant's arguments filed 10/12/2007 have been fully considered but are moot in view of the new grounds of rejection set forth below. Applicants traversed the instant rejection on the grounds that the claims as amended to remove the phrase "ranging from" are now in compliance with 35 USC § 112, 2nd and that the instant rejection should be withdrawn. It is noted that Applicants have amended the instant claims to

recite: "a deletion of nucleotides 324 to 488 of the adenoviral subtype 5 genome."

Contrary to Applicant's assertions, since there is no standard nucleotide numbering set for the E1A promoter, or for the adenoviral subtype 5 genome as recited in the instant claims, it is unclear which nucleotides the range of 324 to 488 are referring to, since the claims are not limited to any particular nucleotide sequence such that one of ordinary skill in the art could clearly distinguish which nucleotides Applicants are referring to.

7. Applicants are reminded of the following statement set forth in the 2nd ¶ of prior Office Action:

8. The rejections under 35 USC 102 and 103 and for double patenting (*set forth in the Non-final Action of 11/20/2006*) are withdrawn due to the amendments of claims 25 and 34 requiring the deletion of nucleotides 324 to 488 of the Ad5 genome. However, as indicated below these limitations in their present form are indefinite and include new matter. Should the limitations be deleted, rather than revised, reinstatement of the withdrawn rejections may be necessary.

Conclusion

9. Claims 43-44 and 48 remain allowable over the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE